

Remarks

The only remaining issues are whether claims 1-29 and 31-44 are anticipated under 35 U.S.C. § 102(a), or in the alternative, whether they are obvious under 35 U.S.C. § 103(a), over Folkesson *et al.* Claims 1-29 and 31-44 are directed to therapeutic agents and processes for treating acute lung injury resulting from indirect causes by way of an anti-IL-8 antibody. Folkesson does not anticipate or render obvious the claims because it neither discloses or suggests treatment of acute lung injury resulting from indirect causes.

Rejection Under 35 U.S.C. § 102

The pending claims stand rejected under 35 U.S.C. § 102(a) as it is alleged that Folkesson discloses a treatment for direct lung injury resulting from acid inhalation, and indirect and direct injury are inherently the same. Applicant respectfully traverses the rejection.

As noted above, the pending claims are directed to therapeutic agents and processes for treating acute lung injury resulting from indirect causes. It is clear from the specification and the art that acute lung injury resulting from direct causes is entirely different than acute lung injury resulting from indirect causes. The specification notes that aspiration, diffuse pulmonary infection, near-drowning, inhalation of irritant gas, and lung contusion are causes of direct injury, while indirect injury results from an entirely different set of causes, such as sepsis syndrome, severe nonthoracic trauma, hypertransfusion during emergency resuscitation, and then artificial cardiopulmonary bypass surgery (page 3, line 17 to 22). Furthermore, physicians classify acute respiratory distress syndrome resulting from direct causes as a different condition than acute respiratory distress syndrome resulting from indirect causes, as evidenced in Bernard *et al.*, *Am J Respir Crit Care Med* Fall 149: 818-824 (1994), which was forwarded to the Examiner on 29 September 2000.

Moreover, it is appreciated in the art that while one drug may have an affect on lung injuries resulting from direct causes, that drug may exert a completely different effect on lung injuries resulting from indirect causes. In particular, it has been demonstrated that lidocaine can mitigate the affects of direct lung injury caused by acid aspiration, while on the other hand, the same drug has little effect on indirect lung injury caused by endotoxin infusion. This distinction between direct injury and indirect injury was reported in Nishina *et al.*, *Anesthesiology* 88: 1300-1309 (1998) and Nishina *et al.*, *Anesthesiology* 83: 169-177 (1995), which were forwarded to the Examiner on 27 September 2000. Hence, direct injury and indirect injury are classified as two distinct conditions in the art and have been proven to be clinically divergent.

Folkesson discusses the affects of an anti-IL-8 monoclonal antibody administered to acid-instilled rabbits. The document does not discuss a treatment of direct lung injury resulting from causes other than acid inhalation, and the document certainly does not mention treatment of acute lung injury resulting from indirect causes.

It is well settled that a document may not be anticipatory if it does not disclose all of elements of a claim. It is also well settled that an Office action must provide factual and technical grounds establishing that an inherent feature necessarily flows from the teachings of the prior art. *See Ex part Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Int. 1990). The Court of Appeals for the Federal Circuit has added that inherency may not be established by probabilities or possibilities. *Continental Can Co. U.S.A., Inc. v. Monsanto Co.*, 948 F2d 1264, 1268-69, 20 USPQ.2d 1746, 1749 (Fed. Cir. 1991) citing *In re Oelrich*, 666 F2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Because Folkesson fails to disclose a treatment of acute lung injury resulting from indirect causes using an anti-IL-8 antibody, the document does not anticipate claims 1-29 and 31-44 as it does not disclose each and every element of the claims. Moreover, it does not necessarily flow from Folkesson's discussion of mitigating direct lung injury that inhibition of

the IL-8 pathway would mitigate indirect lung injury. As noted above, the art classifies direct and indirect injury as two separate injuries and it has been demonstrated that treatments for direct injuries have been ineffective for treating indirect injuries. Moreover, the Office actions have not provided any factual and technical grounds required by the courts for establishing that treatment of indirect injury necessarily flows from Folkesson.

If the Examiner is postulating that inhibition of the IL-8 pathway would possibly or probably mitigate indirect lung injury based on Folkesson, the Court of Appeals for the Federal Circuit has specified that such possibilities or probabilities improperly form the basis for inherency. Therefore, the burden for establishing that treatment of indirect lung injury necessarily flows from Folkesson has not been met, and it is respectfully requested that the rejection of claims 1-29 and 31-44 under 35 U.S.C. § 102(a) be withdrawn.

Rejection of the Pending Claims Under 35 U.S.C. § 103

Claims 1-29 and 31-44 stand rejected under 35 U.S.C. § 103 over Folkesson. Applicant respectfully traverses the rejection. As noted above, Folkesson is limited to treatment of direct lung injury caused by acid inhalation, and does not mention treatment of indirect lung injury. Therefore, Folkesson does not suggest or result in the claimed therapeutic agents and treatments of indirect lung injury, and only a modification of Folkesson could possibly render the claims obvious. It is respectfully submitted that the Office Action does not provide a motivation for modifying Folkesson to a treatment of indirect lung injury.

If the motivation for modifying Folkesson lies in the rationale that it would be obvious to try the methods discussed in the document for treating indirect lung injury, the Court of Appeals for the Federal Circuit has stated that such a motivation does not exist where there is no reasonable likelihood of success. *In re Dow Chemical*, 837 F.2d at 471, 5 USPQ.2d at 1530 (Fed. Cir. 1988). The art has made it clear that applying the method of Folkesson to indirect

lung injury had no reasonable likelihood of success, because it was known that treatments effective for direct lung injury did not necessarily mitigate indirect injury, as noted above in the case of lidocaine. Thus, because there was no reasonable likelihood of success for applying the methods discussed in Folkesson to treatment of indirect lung injury, there existed no motivation to modify the document .

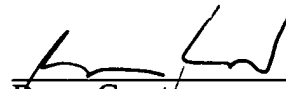
If the motivation for modifying Folkesson is based upon facts within the personal knowledge of the Examiner, Applicant requests that the Examiner document those specific facts in an affidavit. 37 C.F.R. §1.104(d)(2) and MPEP 2144.03. Thus, a *prima facie* case of obviousness has not been established because the Office action does not articulate a motivation for modifying Folkesson, and it is respectfully requested that the rejection of claims 1-29 and 31-44 under 35 U.S.C. §103 be withdrawn.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 350292000500. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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